State of Utah
Administrative Rule Analysis

NOTICE OF PROPOSED RULE

The agency identified below in box 1 provides notice of proposed rule change pursuant to *Utah Code* Sections 63-46a-4. Please address questions regarding information on this notice to the agency. The full text of all rule filings is published in the *Utah State Bulletin* unless excluded because of space constraints. The full text of all rule filings my also be inspected at the Division of Administrative Rules.

DAR file no:		Date filed:	
Utah Admin. Code ref. (R no.):	R156-37	Time filed:	
Changed to Admin. Code Ref. (R no.):			

1.	Agency:	Commerce/Division of Occupational and Professional Licensing		
	Room no.:			
	Building:	Heber M. Wells Building		
	Street address 1:	160 East 300 South		
	Street address 2:			
	City, state, zip:	Salt Lake City UT 84111-2316		
	Mailing address 1:	PO Box 146741		
	Mailing address 2:			
	City, state, zip:	Salt Lake City UT 84114-6741		
	Contact person(s):			
	Name:	**Phone:**	**Fax:**	**E-mail:**
	Diana Baker	801-530-6179	801-530-6511	dbaker@utah.gov

(Interested persons may inspect this filing at the above address or at DAR between 8:00 a.m. and 5:00 p.m. on business days.)

2.	**Title of rule or section** (catchline)**:**
	Utah Controlled Substances Act Rules
3.	**Type of notice:**
	New ___; Amendment XX; Repeal ___; Repeal and Reenact ___
4.	**Purpose of the rule or reason for the change:**
	As a result of recent legislation identified below amendments are being proposed with respect to the Controlled Substance Database. Proposed rule amendments in this rule filing: (1) will require weekly data submissions by pharmacies to the Controlled Substance Database beginning July 15, 2008; (2) implement the real time pilot program established in HB 119 which was passed during the Legislature's 2008 General Session; (3) clarify database access by the Department of Health; (4) clarify the prohibition against individuals requesting an accounting from the Division detailing persons and entities who had requested database information about the individual; and (5) update statute citations regarding Title 63 as a result of HB 63 passed during the Legislature's 2008 General Session.
5.	**This change is a response to comments from the Administrative Rules Review Committee.**
	Yes ___; No XX
6.	**Summary of the rule change:**

	Section 302 - updated Title 63 statute citation. Section 609, paragraph (1) - amendments are proposed to address necessary changes to the receipt of database information from pharmacies with all of the advancement of technology available for transmission of the required data. Section 609, paragraph (4) - amendments are proposed to require that data be collected more frequently than in the past and explains how separate entities should comply. Proposed weekly reporting to the Controlled Substance Database will begin July 15, 2008 if the proposed amendments to the rule are made effective. New Sections 609a and 609b are being added to identify information that must be submitted to the database manager for implementation of the real time pilot program and to identify the limitations on the access to real time database information, those individuals allowed to access the real time information and the standards and procedures for access to the real time pilot program. Section 610, paragraph (4) - amendments are proposed which clarify the prohibition against an individual requesting an accounting from the Division of persons and entities that have received or requested database information about an individual. Section 610, paragraph (7) - amendments are proposed to reflect the way in which the Utah Department of Health is to conduct research using the database information and due to the increasing size of the data, a larger secure computer is required.
7.	**Aggregate anticipated cost or savings to:**
	A) State budget:
	The Division anticipates it will incur minimal costs of approximately $50 to reprint the rule once the proposed amendments are made effective. Any costs incurred will be absorbed in the Division's current budget. The Department of Health may incur some costs to ensure the use of a secure database computer system to store electronic data obtained from the Controlled Substance Database. The Division does not know an amount for the secure database computer system and the Department of Health may already have such a system in place.
	B) Local government:
	Proposed amendments do not apply to local governments, therefore no costs or savings are anticipated. Proposed amendments only apply to regulated/licensed pharmacies who submit controlled substance prescription data to the Utah Controlled Substance Database and to Department of Health personnel.
	C) Small businesses (fewer than 50 employees) AND persons other than businesses:
	The Division anticipates there will be no costs or savings associated with this rule filing to the general public since the proposed rule amendments clarify existing provisions regarding methods of transferring data to the Controlled Substance Database, time frames and formats for transferring of data and Database access by the Department of Health. The public is not responsible for submitting information to the Controlled Substance Database. That responsibility lies with the licensed pharmacy who is filling a controlled substance prescription for a member of the general public. The Division anticipates there may be some additional costs to regulated/licensed pharmacies only as a result of these proposed amendments. It should be noted that some of the licensed pharmacies may be considered a "small business". The proposed amendments are increasing the submittal time of prescription data from pharmacies to the Controlled Substance Database from weekly, bi-weekly or monthly to at least one time per week. Pharmacies may also need to reconfigure data to comply with the proposed amendments. The Division is unable to determine any exact costs to licensed pharmacies due to the diverse nature and size of pharmacies involved ranging from chain size pharmacies to small, locally owned pharmacies. The Division anticipates approximately 510 licensed pharmacies will be impacted by the proposed amendments. It should also be noted that costs for pharmacies who are selected to participate in the real time pilot program were considered in the passage of HB 119.
8.	**Compliance costs for affected persons** ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization or any character other than an agency)**:**

	The Division anticipates there may be some additional costs to regulated/licensed pharmacies only as a result of these proposed amendments. The proposed amendments are increasing the submittal time of prescription data from pharmacies to the Controlled Substance Database from weekly, bi-weekly or monthly to at least one time per week. Pharmacies may also need to reconfigure data to comply with the proposed amendments. The Division is unable to determine any exact costs to licensed pharmacies due to the diverse nature and size of pharmacies involved ranging from chain size pharmacies to small, locally owned pharmacies. The Division anticipates approximately 510 licensed pharmacies will be impacted by the proposed amendments. It should also be noted that costs for pharmacies who are selected to participate in the real time pilot program were considered in the passage of HB 119.
9.	**Comments by the department head on the fiscal impact the rule may have on businesses:**
	This rule filing clarifies existing provisions regarding methods of transferring data into the Controlled Substance Database, requires weekly data submissions by pharmacies, clarifies provisions regarding Database access by the Department of Health and as required by new legislation, implements a pilot program for real-time transfer of data to the Database. It is anticipated that the weekly and real-time transfer of data could create additional costs for pharmacies. However, that cost is difficult to estimate and may vary among pharmacies. Francine A. Giani, Executive Director
10.	**This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws.** **State code or constitution citations** (required)**:**
	Subsections 58-1-106(1)(a), 58-37-6(1)(a) and 58-37-7.5(7)
11.	**This rule adds, updates, or otherwise changes the following titles of materials incorporated by references** (a copy of materials incorporated by reference must be submitted to DAR; if none, leave blank)**:**
12.	**The public may submit written or oral comments to the agency identified in box 1.** (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the *Utah State Bulletin*. See Section 63-46a-5 and Rule R15-1 for more information.)

A) Comments will be accepted until 5:00 p.m. on (mm/dd/yyyy)**:**	07/01/2008

B) A public hearing (optional) will be held:

on (mm/dd/yyyy)**:**	**at** (time)**:**	**At** (place)**:**
06/24/2008	9:00 am	160 East 300 South, Conference Room 474 (4th floor), Salt Lake City, Utah

13.	**This rule change may become effective on** (mm/dd/yyyy)**:** 07/08/2008
	NOTE: The date above is the date on which this rule MAY become effective. It is *NOT* the effective date. After the date designated in Box 12(A) above, the agency *must* submit a Notice of Effective Date to the Division of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.
14.	**Indexing information -- keywords** (maximum of four, in lower case, except for acronyms (e.g., "NASA") or proper nouns (e.g., "Medicaid")**:**

	controlled substances	licensing

15.	**Attach an RTF document containing the text of this rule change** (filename)**:**	R156-37.pro

To the agency: Information requested on this form is required by Sections 63-46a-4, 5, 6, and 10. Incomplete forms will be returned to the agency for completion, possibly delaying publication in the *Utah State Bulletin*, and delaying the first possible effective date.

AGENCY AUTHORIZATION

Agency head or designee, and title:	F. David Stanley, Director	**Date** (mm/dd/yyyy)**:**	05/12/2008

R156. Commerce, Occupational and Professional Licensing.
R156-37. Utah Controlled Substances Act Rules.
R156-37-302. Qualifications for Licensure - Application Requirements.

(1) An applicant for a controlled substance license shall:

(a) submit an application in a form as prescribed by the division; and

(b) shall pay the required fee as established by the division under the provisions of Section [~~63-38-3.2~~]63J-1-303.

(2) Any person seeking a controlled substance license shall:

(a) be currently licensed by the state in the appropriate professional license classification as listed in R156-37-301 and shall maintain that license classification as current at all times while holding a controlled substance license; or

(b) be engaged in the following activities which require the administration of a controlled substance but do not require licensure under Subsection (a):

(i) animal capture for transport or relocation as an employee or under contract with a state or federal government agency; or

(ii) other activity approved by the Division in collaboration with the appropriate board.

(3) The division and the reviewing board may request from the applicant information which is reasonable and necessary to permit an evaluation of the applicant's:

(a) qualifications to engage in practice with controlled substances; and

(b) the public interest in the issuance of a controlled substance license to the applicant.

(4) To determine if an applicant is qualified for licensure, the division may assign the application to a qualified and appropriate licensing board for review and recommendation to the division with respect to issuance of a license.

R156-37-609. Controlled Substance Database - Procedure and Format for Submission to the Database.

(1) In accordance with Subsections 58-37-7.5(6)(a), the format in which the information required under Section 58-37-7.5 shall be submitted to the administrator of the database is:

(a) electronic data via telephone modem;

(b) electronic data stored on floppy disk or compact disc (CD);[~~or~~]

(c) electronic data sent via electronic mail (e-mail) if encrypted and approved by the database manager[~~.~~];

(d) electronic data sent via a secured internet transfer

method, including but not limited to, FTP site transfer and HyperSend; or

(e) any other electronic method preapproved by the database manager.

(2) The required information may be submitted on paper, if the pharmacy or pharmacy group submits a written request to the division and receives prior approval.

(3) The division will consider the following in granting the request:

(a) the pharmacy or pharmacy group has no computerized record keeping system upon which the data can be electronically recorded; or

(b) the pharmacy or pharmacy group is unable to conform its submissions to the format required by the database administrator without incurring undue financial hardship.

(4) [~~E~~]As of July 15, 2008, each pharmacy or pharmacy group [~~may submit the data either weekly, bi-weekly, or monthly~~]shall submit all data collected during the preceding seven days at least once per week. If the data is submitted by a single pharmacy entity, the data shall be submitted in chronological order according to the date each prescription was filled. If the data is submitted by a pharmacy group, the data is required to be sorted by individual pharmacy within the group, and the data of each individual pharmacy within the group is required to be submitted in chronological order according to the date each prescription was filled.[~~ Any pharmacy which does not declare its intention for timely submission of data will be presumed to have chosen monthly submission.~~]

(5) The format for submission to the database shall be in accordance with uniform formatting developed by the American Society for Automation in Pharmacy system (ASAP). The division may approve alternative formats or adjustments to be consistent with database collection instruments and contain all necessary data elements.

(6) The pharmacist-in-charge of each reporting pharmacy shall submit a report on a form approved by the division including:

(a) the pharmacy name;

(b) NABP number;

(c) the period of time covered by each submission of data;

(d) the number of prescriptions in the submission;

(e) the submitting pharmacist's signature attesting to the accuracy of the report; and

(f) the date the submission was prepared.

R156-37-609a. Controlled Substance Database - Reporting Procedure and Format for Submission to the Database for

Pharmacies and Pharmacy Groups Selected by the Division for the Real Time Pilot Program.

(1) In accordance with Subsection 58-37-7.8(8), the information required under Section 58-37-7.5 shall be submitted to the Division's database manager by licensees designated by the Division to participate in the real time reporting pilot program in the following format:

(a) electronic data using the software provided by the Division or software approved by the Division; and

(b) using the real time data transmission system established by the Division.

(2) Each pharmacy or pharmacy group shall enter and submit data required under Section 58-37-7.5 as soon as the data is available to the pharmacy or pharmacy group.

(3) The format for submission to the database shall be in accordance with the uniform formatting developed by the American Society for Automation in Pharmacy System (ASAP). The Division may approve alternative formats.

(4) The pharmacist-in-charge of each reporting pharmacy or pharmacy group shall be responsible for compliance with this rule.

R156-37-609b. Controlled Substance Database - Limitations on Access to Real Time Database Information - Individuals Allowed to Access - Standards and Procedures for Access to Real Time Pilot Program.

(1) In accordance with Subsection 58-37-7.8(8), access to information contained in the controlled substance database is limited to individuals who are designated by the Division to participate in the real time pilot program, as follows:

(a) personnel employed by federal, state and local law enforcement agencies;

(b) pharmacists licensed to dispense controlled substances in Utah;

(c) practitioners licensed to prescribe controlled substances in Utah; and

(d) employees of the Department of Health who have previously been approved by the Division to access controlled substance database information in furtherance of the Pain Medication Management and Education Program.

(2) All individuals who are granted access to information in the controlled substance database via the real time pilot program shall provide any documentation requested by the Division's database manager to confirm the individual's identity. The individual will then be provided a username, password, and PIN number by which the individual will access the information contained in the database. Pursuant to Subsection

58-37-7.5 (9), (10), and (11), it is unlawful for an authorized user to allow another individual to use the authorized user's assigned username, password and PIN number.

(3) Personnel employed by federal, state, and local law enforcement agencies may access only information related to a current investigation involving controlled substances being conducted by that agency.

(4) Pharmacists licensed to dispense controlled substances in Utah may access only information related specifically to a current patient to whom that pharmacist is dispensing or is considering dispensing any controlled substance.

(5) Practitioners licensed to prescribe controlled substances in Utah may access only information related specifically to a current patient of the practitioner, to whom the practitioner is prescribing or is considering prescribing any controlled substance.

(6) Employees of the Department of Health who have been previously approved by the Division to access controlled substance database information in furtherance of the Pain Medication Management and Education Program may access only information in order to conduct scientific studies to evaluate opioid use and opioid-related morbidity and ways to reduce deaths and other harm from improper or risky prescribing and dispensing practices as codified in Section 26-1-36.

R156-37-610. Controlled Substance Database - Limitations on Access to Database Information - Standards and Procedures for Identifying Individuals Requesting Information.

(1) In accordance with Subsections 58-37-7.5(8)(a) and (b), the division director shall designate in writing those individuals within the division who shall have access to the information in the database.

(2) Personnel from federal, state or local law enforcement agencies may obtain information from the database if the information relates to a current investigation being conducted by such agency. The manager of the database may also provide information from the database to such agencies on his own volition when the information may reasonably constitute a basis for investigation relative to violation of state or federal law.

(3) In accordance with Subsections 58-37-7.5(5)(c), (6)(b), (7)(b), and (8)(d) and (e), the database manager may provide information from the database to licensed practitioners having authority to prescribe controlled substances and to licensed pharmacists having authority to dispense controlled substances. The database manager may provide the information on his own volition to accomplish the stated purposes set forth in Subsection 58-37-7.5(5).

(4) Any individual may request information in the database relating to that individual's [~~receipt of~~]controlled substances receipt history. An individuals may not request or receive an accounting of persons or entities that have requested or received information about the individual. Upon request for database information on an individual who is the recipient of a controlled substance prescription entered in the database, the manager of the database shall make available database information exclusively relating to that particular individual's controlled substance receipt history under the following limitations and conditions:

(a) The requestor seeking database information personally appears before the manager of the database, or a designee, with picture identification confirming his identity as the same person on whom database information is sought.

(b) The requestor seeking database information submits a signed and notarized request executed under the penalty of perjury verifying his identity as the same person on whom database information is sought, and providing their full name, home and business address, date of birth, and social security number.

(c) The requestor seeking database information presents a power of attorney over the person on whom database information is sought and further complies with the following:

(i) submits a signed and notarized request executed by the requestor under the penalty of perjury verifying that the grantor of the power of attorney is the same person on whom database information is sought, including the grantor's full name, address, date of birth, and social security number; and

(ii) personally appears before the manager of the database with picture identification to verify personal identity, or otherwise submits a signed and notarized statement executed by the requestor under the penalty of perjury verifying his identity as that of the person holding the power of attorney.

(d) The requestor seeking database information presents verification that he is the legal guardian of an incapacitated person on whom database information is sought and further complies with the following:

(i) submits a signed and notarized request executed by the requestor under the penalty of perjury verifying that the incapacitated ward of the guardian is the same person on whom database information is sought, including the ward's full name, address, date of birth, and social security number; and

(ii) personally appears before the manager of the database with picture identification to verify personal identity, or otherwise submits a signed and notarized statement executed by the requestor under the penalty of perjury verifying his

identity as that of the legal guardian of the incapacitated person.

(e) The requestor seeking database information shall present a release-of-records statement from the person on whom database information is sought and further complies with the following:

(i) submits a verification from the person on whom database information is sought consistent with the requirements set forth in paragraph (4)(b);

(ii) submits a signed and notarized release of records statement executed by the person on whom database information is sought authorizing the manager of the database to release the relevant database information to the requestor; and

(iii) personally appears before the manager of the database with picture identification to verify personal identity, or otherwise submits a signed and notarized statement executed by the requestor under the penalty of perjury verifying his identity as that of the requestor identified in the release of records;

(5) Before data is released upon oral request, a written request may be required and received.

(6) Database information may be disseminated either orally, by facsimile or by U.S. mail.

(7) The Utah Department of Health may access Database information for purposes of scientific study regarding public health. To access information, the scientific investigator must:

(a) show the research is an approved project of the Utah Department of Health;

(b) provide a description of the research to be conducted[~~,~~] including a research protocol[~~s~~] for the project and a description of the data [~~needs~~]needed from the Database to conduct that research;

(c) provide assurances and a plan that demonstrates all Database information will be maintained securely, with access only permitted by the scientific investigator;

(d) provide for electronic data to be stored on a [~~stand alone~~]secure database computer system with access only allowed by the scientific investigator; and

(e) pay all relevant expenses for data transfer and manipulation.

KEY: controlled substances, licensing
Date of Enactment or Last Substantive Amendment: [~~October 22, 2007~~]2008
Notice of Continuation: March 15, 2007
Authorizing, and Implemented or Interpreted Law: 58-1-

106(1)(a); 58-37-6(1)(a); 58-37-7.5(7)